UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Certain cases	)	

ORDER AND REASONS

Before the Court is a Motion for Reconsideration of Order Granting in Part Defendants' Motion for Summary Judgment on the Claims of Plaintiffs Whose Taxotere Treatment Started Before December 15, 2006 (Doc. 10667). The Court held oral argument on October 6, 2020. For the following reasons, the Motion is **DENIED.**

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second trial is set for 2021.[2]

[1] Docetaxel is the generic version of Taxotere.
[2] The second trial was continued due to the COVID-19 pandemic.

In its Order dated June 1, 2020 (Doc. 10487), this Court granted in part and deferred in part Defendants' Motion for Summary Judgment on the Claims of Plaintiffs Whose Taxotere Treatment Started Before December 15, 2006 (the "Pre-2007 Motion"). In the Pre-2007 Motion, Sanofi argued that many jurisdictions only impose a duty to warn on a manufacturer when the manufacturer knew or should have known of the risk at issue at the time of manufacture.[3] Sanofi averred that Plaintiffs had no evidence to show that Sanofi knew or should have known of a possible causal association between Taxotere and permanent hair loss before December 15, 2006.[4]

In its June 1, 2020 Order, the Court focused on Louisiana law and deferred ruling on the other jurisdictions at issue. The Court found that Plaintiffs failed to create an issue of fact on "whether a reasonably prudent manufacturer would have drawn certain conclusions before December 15, 2006, thereby triggering Sanofi's duty to warn."[5] The Court found it significant that Plaintiffs' own regulatory expert, Dr. David Kessler, opined that Sanofi's duty to warn arose "not later than about 2009 and probably about as early as around 2006."[6] The Court noted that, according to Dr. Kessler, a certain presentation made at a breast cancer conference on December 15, 2006 was "a pretty good cutoff."[7] Dr. Kessler testified that after this presentation, "the bells should be going off" for Sanofi.[8] Without evidence disputing this, the Court found there was no issue of fact for a jury to decide.

The Court then directed the parties to prepare a list of the Louisiana cases that could be dismissed pursuant to the Order. Regarding other

[3] Doc. 8977-2 at 1.
[4] *Id.*
[5] Doc. 10487 at 10.
[6] *Id.* at 6–7.
[7] *Id.*
[8] *Id.*

jurisdictions, the Court ordered as follows: "For the other jurisdictions at issue, the parties are instructed to jointly submit to the Court a chart that groups jurisdictions by use of the same language in defining the standard for 'knowledge.' The Court will then consider the submission and issue rulings as to each group of jurisdictions."[9]

In their Motion for Reconsideration, Plaintiffs now argue that there is "a genuine issue regarding Sanofi's knowledge of irreversible hair loss and whether Sanofi should have drawn certain conclusions that triggered its duty to warn prior to December 15, 2006."[10] Plaintiffs point to opinions that their expert, a biostatistician named Dr. David Madigan, provided in connection with the first bellwether trial. Specifically, Dr. Madigan opined that Sanofi had certain information available to it as early as 2000. Further, Plaintiffs admit that in their opposition to Defendants' Pre-2007 Motion, they inadvertently failed to submit Dr. Madigan's latest report to the Court. Plaintiffs aver that the information in the report further establishes a question of fact for the jury regarding the extent of Sanofi's knowledge before 2007. For these reasons, Plaintiffs ask the Court to revisit its June 1, 2020 Order.

LEGAL STANDARD

The parties dispute which legal standard applies here. Plaintiffs advocate for Federal Rule of Civil Procedure 59(e), which governs final judgments, and Defendants advocate for Federal Rule of Civil Procedure 54(b), which governs interlocutory orders. As Defendants admit, however, the Court's June 1, 2020 Order contemplates the imminent entry of final judgments dismissing the cases of Louisiana Plaintiffs who received Taxotere treatment

[9] *Id.*
[10] Doc. 10667-1 at 2.

before December 15, 2006. Accordingly, the Court finds that Federal Rule of Civil Procedure 59(e) should govern its analysis.

Federal Rule of Civil Procedure 59(e) provides that a party may file a motion to alter or amend a judgment no later than 28 days after the entry of the judgment.[11] "Relief under Rule 59(e) requires a showing of (1) an intervening change in controlling law; (2) new evidence not previously available; or (3) the need to correct a clear legal error or to prevent manifest injustice."[12] The Fifth Circuit has provided several factors to consider when a party seeks to upset a summary judgment by producing additional evidence: "(1) the reasons for the moving party's default, (2) the importance of the omitted evidence to the moving party's case, (3) whether the evidence was available to the movant before the nonmovant filed the summary judgment motion, and (4) the likelihood that the nonmoving party will suffer unfair prejudice if the case is reopened."[13] "These factors . . . are simply illustrative and not exhaustive . . . . Rule 59(e) motions provide the district court with 'considerable discretion.'"[14]

LAW AND ANALYSIS

In their Motion, Plaintiffs argue that there is ample evidence creating an issue of fact on Sanofi's knowledge of irreversible hair loss and whether Sanofi should have drawn certain conclusions that triggered its duty to warn prior to December 15, 2006. Plaintiffs point to expert evidence from their expert biostatistician, Dr. David Madigan, who opined that certain signals

[11] FED. R. CIV. P. 59(e).
[12] Farquhar v. Steen, 611 F. App'x 796, 800 (5th Cir. 2015).
[13] ICEE Distributors, Inc. v. J&J Snack Foods Corp., 445 F.3d 841, 848 (5th Cir. 2006) (citations omitted).
[14] *Id.* (citations omitted).

arose before 2006, and Plaintiffs remind the Court that it rejected Defendants' *Daubert* challenge to Dr. Madigan. Specifically, Plaintiffs highlight the Court's statement that "Dr. Madigan's Report, supplemented by his deposition testimony, leaves no guesswork for Defendants."[15] Plaintiffs note that Dr. Madigan's initial report (the "Initial Report") identified a "safety signal" in 2000, and Plaintiffs argue that this evinces "knowledge at the time the product left the manufacturer's control."[16] Under Louisiana law, such knowledge would trigger Sanofi's duty to warn.[17]

Plaintiffs further argue that Dr. Madigan's supplemental reports are even more precise than his Initial Report. Specifically, Plaintiffs point the Court to a report Dr. Madigan prepared in connection with Plaintiff Cynthia Thibodeaux's case (the "*Thibodeaux* Report"). Plaintiffs admit that they cited the *Thibodeaux* Report in their briefing on Defendants' Pre-2007 Motion but failed to attach it. In the Motion for Reconsideration, Plaintiffs explain that the parties have been working remotely due to the COVID-19 pandemic, and this was the reason for the oversight. Plaintiffs note that Defendants were familiar with the *Thibodeaux* Report and had deposed Dr. Madigan on it.

In the *Thibodeaux* Report, Dr. Madigan provides that in 2003, the association between Taxotere and permanent alopecia became statistically significant.[18] Testifying at depositions, Dr. Madigan repeatedly affirmed this.[19] Based on this evidence, Plaintiffs argue that there is an issue of fact regarding whether Sanofi had knowledge to trigger its duty to warn prior to December 15, 2006. Plaintiffs further argue that reconsideration is warranted to prevent the potential dismissal of over 1,000 cases due to counsel's oversight.

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[15] Doc. 10667-1 at 8.
[16] *Id.* at 9.
[17] *See* Doc. 10487 at 5.
[18] Doc. 10667-9 at 11–12.
[19] *Id.* at 12.

In response, Defendants argue that Plaintiffs' evidence still fails to create an issue of fact on the Pre-2007 Motion. Defendants emphasize that Dr. Madigan is not a regulatory expert and that he only offered statistics to assist Plaintiffs' regulatory expert, Dr. Kessler, in deciding when Sanofi's duty to warn arose. Defendants note that Dr. Kessler considered all of Dr. Madigan's reports before opining that Sanofi's duty to warn was triggered on December 15, 2006. Lastly, Defendants argue that the Court should not consider the *Thibodeaux* Report. Defendants take issue with Plaintiffs' explanation for failing to submit the *Thibodeaux* Report, noting that Plaintiffs filed their opposition on February 7, 2020, before the first case of COVID-19 was reported in New Orleans and before the city issued a stay-at-home order.

As an initial matter, the Court notes that insofar as Plaintiffs rely on certain language from this Court's *Daubert* ruling on Dr. Madigan, Plaintiffs take the language out of context. In large part, the Court's *Daubert* ruling addressed whether Plaintiffs' experts had offered reliable testimony on general causation.[20] Defendants had argued that Dr. Madigan did not adequately articulate his opinion on the association between Taxotere and permanent alopecia. Considering this, the Court quoted Dr. Madigan's deposition, during which he stated that "there is a causal effect established here [between Taxotere and irreversible alopecia]."[21] The Court concluded, then, that "Dr. Madigan's report, supplemented by his deposition testimony, leaves no guesswork for Defendants."[22] Accordingly, this statement by the Court had nothing to do with Dr. Madigan's opinions on *when* the association between Taxotere and permanent alopecia became statistically significant. It related only to whether Dr. Madigan had adequately disclosed his opinion.

[20] *See* Doc. 8094.
[21] *Id.* at 7.
[22] *Id.*

In ruling on the Pre-2007 Motion, the Court admittedly paused upon reading this paragraph in Plaintiffs' Response to Defendants' Statement of Facts and Plaintiffs' Counterstatement of Facts (Doc. 9231-1):

> Plaintiffs' expert biostatistician, Dr. David Madigan, analyzed data from Sanofi's annual Safety Update Reports from the TAX316 Study, which showed that by 2004 Sanofi was witnessing persisting, unresolved alopecia occur at a 2.42 times higher rate with Taxotere than without it. (Rule 26 Report of Dr. David Madigan, p. 26 at Table 9, Oct. 20, 2019.) This rate jumped to 2.60 in 2005 and remained at 2.60 in all subsequent years. (*Id.*) When the GEICAM data were included in those numbers, the rates increase to 2.47 in 2004 and 2.63 in subsequent years. (*Id.*) Dr. Madigan's calculations for each year are all statistically significant with p-values ranging from 0.013 to 0.020. (*Id.*)[23]

The Court believed Plaintiffs' statement had the potential to create an issue of fact and defeat Defendants' Pre-2007 Motion. The Court was puzzled, however, by the citation to Table 9 of Dr. Madigan's "Rule 26 Report," which the Court now knows was inadvertently omitted from Plaintiffs' submission. After searching the record in vain to find support for this paragraph, the Court found that Plaintiffs fell short of creating an issue of fact.

The Court has now studied Table 9 of the *Thibodeaux* Report, and the Court sees the disparity in the numbers that Plaintiffs describe. The Court sees that in 2004 persistent hair loss was occurring at a 2.42 times higher rate in Taxotere regimens as opposed to non-Taxotere regimens.[24] In addition, the Court sees the "jump" in 2005 that Plaintiffs highlight.[25] Ultimately, however, the Court finds that this is not enough to create an issue of fact for the jury.

[23] Doc. 9231-1 at 10.
[24] Doc. 10667-12 at 27.
[25] *Id.*

The statistics are only the first piece of the puzzle. To defeat Defendants' Motion for Summary Judgment, Plaintiffs would need another qualified expert to put Dr. Madigan's statistics in context and explain that a reasonably prudent manufacturer could have looked at these numbers and determined that Taxotere was causing permanent hair loss or potentially causing permanent hair loss. The numbers alone simply do not create an issue of fact for the jury. Accordingly, the Court will not reconsider its June 1, 2020 Order.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Reconsideration of Order Granting in Part Defendants' Motion for Summary Judgment on the Claims of Plaintiffs Whose Taxotere Treatment Started Before December 15, 2006 (Doc. 10667) is **DENIED**. The parties should proceed with preparing a chart that groups jurisdictions by use of the same language in defining the standard for "knowledge." The Court will then consider the submission and issue rulings as to each group of jurisdictions.

New Orleans, Louisiana this 18th day of December, 2020.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE